

PATENT  
Client-Matter No.: 66783-142

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of )  
Targan et al. )  
 )  
Serial No: 10/723,164 )  
 )  
Filed: November 26, 2003 )  
 )  
For: METHODS OF ASSESSING )  
CROHN'S DISEASE PATIENT )  
PHENOTYPE BY I2, OMPC AND )  
ASCA SEROLOGIC RESPONSE )  
 )

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**SMALL ENTITY STATEMENT**

The U.S. Patent and Trademark (USPTO) permits parties that establish status as a Small Entity to pay certain reduced fees (all citations to 37 C.F.R. § 1.27 except as noted). To be entitled to Small Entity Status, a party must be at least one of the following:

**(1) Individual person:**

An individual person, including an inventor and persons to whom an inventor has transferred some rights in the invention. § 1.27(a)(1).

**(2) Small business concern:**

A business concern whose number of employees, including affiliates, does not exceed 500 persons. § 1.27(a)(2) (incorporating 13 C.F.R. § 121.802).

“Business concern” means individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative. If the concern is a joint venture, participation by foreign business entities may not be more than 49%. 13 C.F.R. § 121.105.

The “number of employees” is the average number of employees, including the employees of its domestic and foreign affiliates, based on

numbers of employees for each of the pay periods for the preceding completed 12 calendar months. "Employees" includes all individuals employed on a full-time, part-time, temporary, or other basis. Part-time and temporary employees are counted the same as full-time employees. If a concern has not been in business for 12 months, use the average number of employees for each of the pay periods it has been in business. 13 C.F.R. § 121.106.

Concerns are "affiliates" of each other when one concern directly or indirectly controls or has the power to control the other, or when a third party or parties controls or has the power to control both concerns. 13 C.F.R. § 121.103(a).

**(3) Nonprofit organization:**

A university or other institution of higher education located in any country. § 1.27(a)(3) (ii)(A).

An organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a). Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(B),(D).

A nonprofit scientific or educational organization qualified under a nonprofit organization statute of a U.S. state. Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(C),(D).

Please note that a license to the Government resulting from a rights determination under Executive Order 10096 does not constitute a license that would prohibit claiming Small Entity Status. Similarly, for small business concerns and nonprofit organizations, a license to a Federal agency resulting from a funding agreement with that agency under 35 U.S.C. § 202(c)(4) is not a license that would prohibit claiming Small Entity Status. § 1.27(a)(4).

I hereby assert that I am empowered to sign on behalf of the party identified below ("Party"). Persons empowered to sign include, but are not limited to, an inventor him- or herself or an authorized officer of an assignee or licensee. *See* § 1.27(c)(2).

I have made a determination of the Party's entitlement to Small Entity Status, including a determination that all parties holding rights in the invention qualify for Small Entity Status. § 1.27(f).

Inventors: Targan et al.  
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I hereby assert that the Party has not assigned, granted, conveyed or licensed--and is under no obligation under contract or law to do so--any rights in the invention to any other party that would not qualify as a Small Entity. Separate assertions of Small Entity Status should be obtained from each party having rights to the invention.

I hereby assert that the Party is entitled to be accorded Small Entity Status by the USPTO for the application or patent identified above. § 1.27(c)(1).

I understand that Small Entity Status must be newly determined when the issue fee and each maintenance fee is due. If there is any change resulting in loss of entitlement to Small Entity Status, I acknowledge the duty to file a notification to the USPTO in this application or patent before or upon paying the fee. § 1.27(g).

I understand that Small Entity Status must be separately established in any related application, including continuation, divisional, continuation-in-part, continued prosecution application or reissue application. § 1.27(c)(4).

I understand that any attempt to establish Small Entity Status improperly, deceptively or fraudulently will be considered a fraud practiced on the USPTO and may result in abandonment of the application or jeopardize the validity and enforceability of any resulting patent. § 1.27(h).

11/9/04  
Date



Name: Peter E. Braverman  
Title: Senior Vice President for Legal Affairs  
and General Counsel

CEDARS-SINAI MEDICAL CENTER  
8700 Beverly Boulevard  
Los Angeles, California 90048-1865

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PATENT & TRADEMARK OFFICE

Docket No.: 066783-0142

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

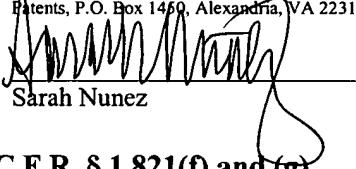
Applicant : Targan, Stephan R., et al.  
Appl. No. : 10/723,164  
Filed : November 26, 2003  
Title : METHODS OF ASSESSING  
CROHN'S DISEASE PATIENT  
PHENOTYPE BY I2, OMPC AND  
ASCA SEROLOGIC RESPONSE  
Grp./A.U. : 1644  
Examiner: : Unassigned

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Sarah Nunez

**STATEMENT UNDER 37 C.F.R. § 1.821(f) and (g)**

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

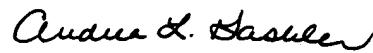
Sir:

I hereby state that the content of the paper and computer readable copies of the  
Sequence Listing, submitted in accordance with 37 CFR § 1.821(c) and (e), respectively, are  
the same.

I hereby state that the submission, filed in accordance with 37 C.F.R. § 1.821(g)  
herein does not include new matter.

Respectfully submitted,

MCDERMOTT WILL & EMERY LLP

  
Andrea L. Gashler  
Registration No. 41,029

4370 La Jolla Village Drive, Suite 700  
San Diego, CA 92122  
Telephone: 858.535.9001 ALG:reb  
Facsimile: 858.597.1585  
**Date: November 10, 2004**  
SDO 21570-1.066783.0142